BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New Rules I and II pertaining to general Medicaid services, physician administered drugs	))))	NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION

TO: All Interested Persons

1. On March 25, 2008, at 11:00 a.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room, 2401 Colonial Drive, Helena, Montana, to consider the proposed adoption of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process (including reasonable accommodations at the hearing site) or who need an alternative accessible format of this notice. If you need an accommodation, contact the department no later than 5:00 p.m. on March 10, 2008. Please contact Rhonda Lesofski, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena MT 59604-4210; telephone (406)444-4094; fax (406)444-1970; e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

RULE I PHYSICIAN ADMINISTERED DRUGS, DEFINITIONS (1) "Centers for Medicare and Medicaid Services (CMS) Top 20" means the list of National Drug Codes (NDCs) as determined under Section 1927(a)(7)(B) of the Social Security Act requiring the Secretary of CMS to publish a list of the 20 multiple source physician administered drugs with the highest dollar volume dispensed under the Medicaid program.

(2) "Healthcare common procedures coding system (HCPCS)" means the national uniform coding method maintained by the CMS that incorporates the American Medical Association (AMA) Physicians Current Procedural Terminology (CPT) and the three HCPCS unique coding levels, I, II, and III.

(a) For purposes of physician administered drugs, HCPCS refers to billable codes that may be cross-walked to NDCs.

(3) "National Drug Codes (NDC)" means an 11 digit numerical code that identifies the manufacturer, drug, and package size assigned by the Federal Drug Administration (FDA).

(4) "Physician administered drugs" means covered outpatient drugs under section 1927(k)(2) of the Social Security Act that are typically furnished incident to a physician's service.

(a) These drugs are injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting.

(b) Reimbursement for physician administered drugs is allowed only if the drug is a covered drug under 42 USC 1396r-8.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-6-101, MCA

RULE II Physician Administered Drugs, Requirements (1) Effective April 1, 2008, all billable claim lines submitted for physician administered drugs must include the NDC, the corresponding HCPCS code, and the units administered for each code.

(a) Claim lines billed for HCPCS that represent physician administered injections will be denied if there is no NDC on the line.

(b) Reimbursement will be made only on those drugs manufactured by companies that have a signed rebate agreement with the CMS.

(2) The requirements of this rule do not apply to claims reimbursed under all-inclusive payment methodologies.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-6-101, MCA

4. The Department of Public Health and Human Services (the department) is proposing new Rules I and II pertaining to general Medicaid services. The purpose of the proposed rules is to comply with requirements of the Deficit Reduction Act of 2005 (DRA), Public Law No. 109-171 pertaining to prescription drugs under the Medicaid program. Section 6002 of the DRA amends section 1903(i)(10) of the Social Security Act by prohibiting Medicaid Federal Financial Participation (FFP) for physician administered drugs unless states submit the utilization data described in section 1927(a) of the Act. It also amends section 1927 of the Act to require the submission of utilization data for physician administered drugs. This rule was to have been effective January 1, 2008.

The Centers for Medicare and Medicaid Services (CMS) is requiring states to obtain rebates on at least the top 20 multiple source physician administered drugs with the highest dollar volume dispensed under the Medicaid program and manufactured by companies that have a signed rebate agreement with CMS. States may require reporting of National Drug Codes (NDCs) on all physician administered drugs for rebate purposes. Because the cost of programming to collect this data is high and the rebate estimated to be generated by collecting on only the CMS Top 20 is low, the department has elected to enforce collection of all reimbursable NDC codes for rebate purposes.

Because the programming to collect NDCs is complicated and expensive, the Department requested and was granted an extension by CMS. This extension expires March 31, 2008.

RULE I

The proposed rule is to define the terms used in the other proposed rule.

RULE II

The purpose of this rule is to implement the provisions of DRA.

Effective April 1, 2008 the department will require providers to report NDCs along with healthcare common procedures coding system (HCPCS) codes on all payable physician administered drugs. This does not apply to providers who are paid an all inclusive rate per visit (i.e., Rural Health Clinics, Indian Health Services) because the drug is considered bundled into the payment for the primary service provided at the visit.

Payment to the provider for physician administered drugs is currently made using the reimbursement methodology for provider type (i.e., Resource based relative value scale (RBRVS), Outpatient prospective payment system (OPPS), or fee schedule) based on the billed HCPCS code. These reimbursement methodologies will not change.

The department will deny reimbursable claim lines with dates of service on or after April 1, 2008 that do not report an NDC or are not manufactured by companies that have a signed rebate agreement with CMS.

For claims in which a line is denied because of no NDC, providers will have 365 days from the date of service to submit an adjustment or new claim to receive payment. Any impact for lines denied because of no NDC will be due to providers not timely resubmitting corrected claims.

Rebateable drugs are readily available to providers. Over 400 drug manufacturers have signed rebate agreements with CMS. This is the preponderance of companies doing business in the United States. The odds of a provider reporting an NDC that is not manufactured by a company with a signed rebate agreement are nominal.

Persons affected

The proposed change will affect approximately 5000 professional providers (physician, mid-level, etc.) and approximately 350 outpatient providers (hospitals, birthing facilities, etc.).

Fiscal effects

Rebates are obtained from the drug manufacturers within three months of reporting the NDCs. The rebates are deposited into the state general fund and then federal matching assistance percentage (FMAP) is returned to the federal government based on the date of service. The department expects the proposed Rules I and II to bring in rebates of approximately $81,396 for SFY 08 and approximately $325,584 for SFY 09.

SFY 08 expected rebate:
68.53% federal share for April - June = $55,781
31.47% state share for April – June = $25,615
Total SFY 08=$81,396

SFY 09 expected rebate:
68.53% federal share for July - September = $55,781
31.47% state share for July - September = $25,615

68.38% federal share for October - June = $166,976
31.62% state share for October - June = $77,212
Total SFY 09=$325,584

5. The department intends to apply the proposed new rules effective April 1, 2008. Since the billing requirements are simply administrative, there will be no detrimental effects.

6. Interested persons may submit comments orally or in writing at the hearing. Written comments may also be submitted to Rhonda Lesofski, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena MT 59604-4210 no later than 5:00 p.m. on March 27, 2008. Comments may also be faxed to (406)444-1970 or e-mailed to dphhslegal@mt.gov. The department maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. To be included on such a list, please notify this same person or complete a request form at the hearing.

7. An electronic copy of this proposal notice is available through the Secretary of State's web site at http://sos.mt.gov/ARM/Register. The Secretary of State strives to make the electronic copy of this notice conform to the official version of the notice as printed in the Montana Administrative Register, but advises all concerned persons that, in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. The web site may be unavailable at times, due to system maintenance or technical problems.

8. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

9. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct the hearing.

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Rule Reviewer	Director, Public Health and Human Services

Certified to the Secretary of State February 19, 2008.